

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA and the States of ARKANSAS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW **MEXICO, NEW YORK, NORTH** CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, UTAH, VIRGINIA, WISCONSIN, CITY OF CHICAGO, DISTRICT OF **COLUMBIA and CITY OF NEW** YORK ex rel. GERARDO TORRES, M.D.,

Relator-Plaintiff

SHIRE SPECIALTY
PHARMACEUTICALS; SHIRE PLC;
SHIRE US, INC.; SHIRE
PHARMACEUTICALS, INC.; SHIRE,
LLC; SHIRE DEVELOPMENT, INC.;
SHIRE US MANUFACTURING, INC.,

and

v.

NOVEN PHARMACEUTICALS, INC.

Defendants.

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730

CIVIL ACTION NO. 08-4795

JURY TRIAL DEMANDED

FILED

FEB 16 2011

MICHABLE. KUNZ, Clerk By Oep. Clerk

FIFTH AMENDED COMPLAINT FOR DAMAGES AND OTHER RELIEF UNDER THE QUI TAM PROVISIONS OF THE FALSE CLAIMS ACT AND SIMILAR STATE PROVISIONS

Relator-Plaintiff Gerardo Torres, M.D. ("Relator-Plaintiff"), through his undersigned attorneys, on behalf of the United States of America ("United States"), and the State of Arkansas, the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Louisiana, the State of Maryland, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Hampshire, the State of New Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the State of Utah, the Commonwealth of Virginia, the State of Wisconsin, the City of New York, the City of Chicago, in addition to the District of Columbia (collectively, "the States and Cities") (together, with Relator-Plaintiff, the "Plaintiffs"), for his Complaint against Defendants Shire Specialty Pharmaceuticals; Shire plc; Shire US, Inc.; Shire Pharmaceuticals, Inc.; Shire LLC; Shire Development, Inc.; Shire US Manufacturing, Inc. (collectively, "Shire"), and Noven Pharmaceuticals, Inc. ("Noven") (collectively, "Defendants") alleges as follows:

I. INTRODUCTION

1. This is an action, by and through Relator-Plaintiff Gerardo Torres, M.D., to recover treble damages and civil penalties on behalf of the United States and the States and Cities arising from false and/or fraudulent records, statements and claims made, used and/or caused to be made, used or presented by Defendant and/or its agents, and employees in violation of the federal False Claims Act, 31 U.S.C. § 3729 et seq. and the state laws referred to in paragraph 2 of this Complaint.

2. Defendant's acts also constitute violations of THE Arkansas Medical Fraud False Claims Act, Ark. Code. Ann. § 20-77-901 et seq.; the California False Claims Act, Cal. Gov't. Code §12650 et seq.; the Colorado Medicaid False Claims Act, Col. Rev. Stat. § 25.5-4-304 et seq.; the Connecticut Medical Assistance Program False Claims Act, § 17b-301a et seq.; the Delaware False Claims & Reporting Act, 6 Del. C. §1201 et seq.; the Florida False Claims Act, Fla. Stat. Ann. §68.081 et seq.; the Georgia State False Medicaid Claims Act, Ga. Code 49-4-168 et seq.; the Hawaii False Claims Act, Haw Rev. Stat. § 661-21 et seq.; the Illinois Whistle Blower Reward & Protection Act, 740 ILCS § 175/1 et seq.; the State of Indiana False Claims And Whistleblowers Protection Act, Ind. Code Ann. § 5-11-5.5 et seq.; the Louisiana False Claims Act, La. Rev. Stat. Ann. § 46:439.1 et seq.; the Maryland False Health Claims Act, Md. Code Ann. §2-601 et seq.; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §5A et seq.; the State of Michigan Medicaid False Claims Act, Mich. Comp Laws § 400.603,606 and 607; the Minnesota False Claims Act, § 15C.01 et seq.; the State of Montana False Claims Act, Mont. Code Ann. § 17-8-403,17-8-410; the Nevada False Claims Act, Nev. Rev. Stat. Ann. §357.010 et seq.; the New Hampshire False Claims Act, New Hamp. Stat. 167:61-b; the New Jersey False Claims Act, N.J. Stat.. §2A:32C-1-17; the State of New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1-27-14-15; the New York False Claims Act, N.Y. St. Finance Law §187 et seq.; the State of North Carolina False Claims Act, N.C. Gen. Stat. Ann. § 108A-70.10 et seq.; the state of Oklahoma False Claims Act, 63 Okl. St. §5053.1.4; the State of Rhode Island False Claims Acts R.I. Gen. Laws § 9-1/1-3; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §71-5-181 et seq.; the Texas Medicaid Fraud Prevention Act, Tex. Human Res. Code, Ch. 36, §36.101 et seq.; the Utah False Claims Act, Utah Code Ann. § 26-20-1, et seq.; the Virginia Fraud Against Taxpayers Act, Va. Stat. Ch. 842, Art. 19.1, §8.01-216.1 et seq.;

the State of Wisconsin False Claims Act, Wis. Stat. § 20.931; the City of Chicago False Claims Act, Municipal Code of Chicago, §1-22-010-§1-22-060; the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §1-1188.14 *et seq.*; and the City of New York False Claims Act, New York City Administrative Code, §7-801-§7-810 (collectively, the "State False Claims Acts").

- 3. This matter involves illegal marketing practices by Defendant Shire.
- 4. This matter involves illegal manufacturing practices by Defendant Noven.
- 5. On information and belief, since at least 2001, Defendant Shire has been engaged in illegal marketing schemes for, among other things, the purpose of increasing the sale of its drugs Adderall XR® (mixed amphetamine salts) and Vyvanse® (lisdexamfetamine dimesylate).
- 6. Both Adderall XR and Vyvanse are indicated for the treatment of attention deficit hyperactivity disorder ("ADHD"). The active ingredient in both Adderall XR and Vyvanse is amphetamine.
- 7. On information and belief, since at least August 2004, Defendants Shire and Noven have been engaged in illegal marketing schemes for the purpose of increasing the sales of the drug Daytrana[®].
- 8. Daytrana is a methylphenidate transdermal system/stimulant indicated for the treatment of ADHD in children ages six to twelve.
- 9. Relator-Plaintiff Gerardo Torres, M.D. is the Vice President, Leader, Research and Development, Due Diligence for Shire.
- 10. Dr. Torres previously served as the Vice President, Research and Development, in the ADHD/CNS Business Unit for Shire. In that position, he was responsible for the development and execution of global development plans for Shire's ADHD/CNS business unit

and the development and execution of global medical plans to support effective launches and commercialization of all business unit products.

11. Dr. Torres was also responsible for overseeing all pharmacovigilance and epidemiology efforts from Shires's ADHD/CNS business unit which included interacting with the FDA and foreign regulatory agencies.

II. PARTIES

- 12. The United States of America, and the above-named States and Cities, are the plaintiffs for whom recovery is sought for false and fraudulent claims submitted to Medicaid and other government-funded health programs, including Champus/TriCare and Veteran's Administration funded programs, as well as those of the respective State and City plaintiffs.
- 13. Relator-Plaintiff Gerardo Torres, M.D. is the Vice President, Leader, Research and Development, Due Diligence for Shire and is a citizen and resident of the Commonwealth of Pennsylvania. Dr. Torres brings this action on his own behalf and on behalf of the United States pursuant to 31 U.S.C. § 3730(b)(1) and the respective State and City whistleblower statutes cited in paragraph 2 of this Fifth Amended Complaint.
- 14. Relator-Plaintiff has worked for Shire for more than five years in very senior positions in the company.
- 15. Relator-Plaintiff Torres possesses a Master of Business Administration from Temple University and a doctorate in Medicine from the University of Puerto Rico School of Medicine.
- 16. Upon information and belief, Defendant Shire Specialty Pharmaceuticals is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with its principal place of business in Wayne, Pennsylvania.

- 17. Defendant Shire plc is a company organized and existing under the laws of Jersey, Channel Islands, United Kingdom. Shire plc a global specialty biopharmaceutical company, and has its principal place of business in Hampshire, United Kingdom.
- 18. Defendant Shire US, Inc. is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in Wayne, Pennsylvania.
- 19. Defendant Shire Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Wayne, Pennsylvania.
- 20. Defendant Shire LLC is a limited liability company organized and existing under the laws of the State of Kentucky, with its principal place of business in Florence, Kentucky
- 21. Defendant Shire Development, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Wayne, Pennsylvania.
- 22. Defendant Shire US Manufacturing, Inc. is a corporation organized and existing under the laws of the State of Maryland, with its principal place of business in Owings Mills, Maryland.
- 23. Defendant Shire licenses, develops, sells, manufactures, distributes, markets and promotes Adderall XR and Vyvanse.
- 24. Defendant Shire licenses, develops, sells, distributes, markets and promotes Daytrana.
- 25. Defendant Noven Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Florida, with its principal place of business in Miami, Florida.

6

26. Defendant Noven manufactures Daytrana.

- 27. Defendant Shire licenses, develops, manufactures, sells, distributes, markets and promotes its pharmaceutical products throughout the United States, including in the Eastern District of Pennsylvania.
- 28. Defendant Noven manufactures Daytrana in Miami, Florida for distribution by Shire throughout the United States, including in the Eastern District of Pennsylvania.
- 29. In or around June 2009, Defendant Noven and Hisamitsu Pharmaceutical Co., Inc. ("Hisamitsu") entered into a definitive merger agreement under which Hisamitsu acquired all of Noven's outstanding shares.

III. JURISDICTION AND VENUE

- 30. This is a civil action arising under the laws of the United States to redress violations of 31 U.S.C. §§ 3729-3730. This court has jurisdiction over the subject matter of this action: (i) pursuant to 31 U.S.C. § 3732, which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730; (ii) pursuant to 28 U.S.C. § 1331, which confers federal subject matter jurisdiction; and (iii) pursuant to 28 U.S.C. § 1345, because the United States is a plaintiff.
- 31. This suit is not based upon prior public disclosures of allegations or transactions in a criminal, civil, or administrative hearing, lawsuit or investigation or in a Government Accounting office or Auditor General's report, hearing, audit, or investigation, or from the news media.
- 32. To the extent that there has been a public disclosure unknown to Dr. Torres, Dr. Torres is an original source under 31 U.S.C. § 3730(e)(4) and the State False Claims acts. He has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the government in this Complaint.

IV. FACTUAL ALLEGATIONS

A. Facts Relevant to Adderall XR and Vyvanse Claims

- 33. Adderall XR is a Central Nervous System (CNS) stimulant or amphetamine, approved in the U.S. for the management of ADHD. Adderall XR is currently prescribed to thousands of adults, children, and adolescents diagnosed with ADHD.
- 34. In 2007, Adderall XR had sales of more than \$1.03 billion in the United States, an increase of approximately 19% for the same period in 2006. In 2008, Adderall XR had sales of more than \$1.1 billion in the United States, which accounted for 36% of Shire's revenue.
- 35. Vyvanse is a prodrug of dextroamphetamine, a stimulant, and is indicated for the treatment of ADHD. It is a once-a-day treatment for adults and children who are six to 12 years old with ADHD.
- 36. In 2007, Vyvanse had sales of approximately \$97 million in the United States.

 Datamonitor, a pharmaceutical trade publication, estimates that Vyvanse's sales will reach \$1 billion by 2017.
 - 37. In 2008, Vyvanse had sales of more than \$300 million in the United States.
- 38. Upon information and belief, approximately 20% of the prescriptions for Adderall XR and Vyvanse are paid for by the state and/or federal governments. Upon information and belief, approximately 78% of all ADHD prescriptions were derived from pediatric sales in 2007.

B. Shire Improperly Markets Adderall XR and Vyvanse

- 39. In order to expand the market penetration of Adderall XR and Vyvanse, Shire has engaged in a pattern of mis-marketing each of these medications relating to their efficacy and safety, as well as for "off-label" uses not approved by the FDA.
 - 40. In order to effectuate its off label marketing program Shire has engaged in a

scheme to make false and misleading representations as to the efficacy and safety of Adderall XR and Vyvanse.

- 41. There are a host of drugs indicated for the treatment of ADHD, including, but not limited to, Vyvanse, Adderall XR, Adderall (amphetamine), Concerta (extended release methylphenidate), Straterra (atomoxetine) and Ritalin (methylphenidate).
- 42. FDA regulations provide that promotional materials are false or misleading if they contain a drug comparison that represents or suggests that a prescription drug is more effective than another drug when such has not been demonstrated by substantial evidence or substantial clinical experience.
- 43. Upon information and belief, Shire has promoted Adderall XR as clinically superior to Adderall, methylphenidate and Concerta in numerous sales aids from at least 2001 to today.

 These clinical superiority claims constituted an off-label promotion.
- 44. Shire promoted Adderall XR as being superior to competitors in "normalizing" children with ADHD. The study referenced in support of this claim was not designed to measure the "normalization" of the children in the study. Furthermore, the authors of the study clearly averred that the study was a non-comparative study. Lastly, the comparative analysis between the drugs was a post-hoc analysis of the data. Consequently, the promotion of Adderall XR as being superior to competitors in "normalizing" children constituted a false and misleading promotion. Lastly, Adderall XR is not indicated to "normalize" children with ADHD.
- 45. Shire extensively promoted Adderall XR with implied claims of efficacy that were not supported by substantial evidence or substantial clinical experience.
- 46. Shire extensively promoted Adderall XR as being effective in preventing outcomes allegedly associated with ADHD including, but not limited to, the development of substance use

disorder. None of the studies used in this promotion were supported by substantial evidence or substantial clinical experience.

- 47. Adderall XR is an amphetamine and its prescribing information states that "[a]mphetamines are thought to block the reuptake of norepinephrine and dopamine into the presynaptic neuron and increase the release of these monoamines into the extraneuronal space."
- 48. Despite the indeterminate language in Adderall XR's prescribing information, Shire extensively promoted Adderall XR as having a "unique mechanism of action" in the treatment of ADHD. Specifically, Shire misleadingly promoted that Adderall XR provides direct action on dopamine and norepinephrine when there is no substantial evidence or substantial clinical experience that Adderall XR has any such effect. And, even if there were such evidence, <u>all</u> amphetamines would have such an effect and not just Adderall XR. Consequently, claims that Adderall XR has a "unique", "robust" or "direct" action on norepinephrine and dopamine are patently false.
- 49. Shire also promoted Adderall XR's alleged mechanism of action with the results of studies conducted on rats.
- Shire promoted Adderall XR with the results of the Long Acting Adderall
 Community Assessment Trial ("LADD-CAT") from at least January 2003 through March 2007.
- 51. LADD-CAT was a non-comparative, open-label study comparing Adderall XR to Adderall immediate release, methylphenidate and Concerta.
- 52. Shire promoted LADD-CAT data for over three years before the results of the trial were published in peer-reviewed journal.

- 53. The results from non-comparative, open-label studies do not constitute substantial evidence or substantial clinical experience. The promotion of messages from non-comparative, open-label studies constitute the promotion of false and misleading information.
- 54. During the time Shire promoted LADD-CAT data, the FDA made it abundantly clear to pharmaceutical manufacturers in at least four Warning Letters and one Untitled Letter that the promotion of open-label data to show a drug's superiority is expressly prohibited.
- 55. Shire promoted the LADD-CAT "safety" data to physicians to illustrate the tolerability and safety of Adderall XR even though this data did not correlate with Adderall XR's own prescribing information.

C. Shire Downplays Black Box Warning in Labels

- 56. FDA is responsible for ensuring that drug products are safe and effective for use as directed in the labeling. When a serious risk is identified, FDA works with the drug's sponsor to identify methods to manage that risk. The black box warning is one of these methods.

 Specifically, FDA works with the drug's sponsor on the precise language to be included in the warning on the label.
- 57. Black box warnings are used in labeling to convey serious risks associated with the use of a drug product. The promotional materials of drug products with boxed warnings must present these serious risks in a prominent manner. *See* 21 CFR 202 *et seq*.
- 58. There is a black box warning on each of the amphetamine-based ADHD drugs that warns of the risk of dependency and abuse of the drugs. The black box warning for Adderall XR and Vyvanse reads:

WARNING: POTENTIAL FOR ABUSE

AMPHETAMINES HAVE A HIGH POTENTIAL FOR ABUSE.
ADMINISTRATION OF AMPHETAMINES FOR PROLONGED PERIODS OF
TIME MAY LEAD TO DRUG DEPENDENCE. PARTICULAR ATTENTION

SHOULD BE PAID TO THE POSSIBILITY OF SUBJECTS OBTAINING AMPHETAMINES FOR NON-THERAPEUTIC USE OR DISTRIBUTION TO OTHERS AND THE DRUGS SHOULD BE PRESCRIBED OR DISPENSED SPARINGLY. MISUSE OF AMPHETAMINES MAY CAUSE SUDDEN DEATH AND SERIOUS CARDIOVASCULAR ADVERSE EVENTS.

- 59. However, from 2002 to 2009, Shire failed to prominently display this black box language on Adderall XR promotional material. Thus, Shire failed to present critical information to physicians that would provide physicians with a clear understanding of a potential medical complication associated with Adderall XR, thus undermining the potential consequences to patients and public safety.
- 60. Of all the drugs indicated for the treatment of ADHD, only Straterra and Intuniv, which was recently approved, are not stimulants.

D. Shire Improperly Promotes Vyvanse As Non-Abuseable

- 61. Vyvanse is an amphetamine "prodrug". A "prodrug" is a pharmaceutical that is administered in an inactive form (or significantly less active). Once metabolized, the prodrug is metabolized in the body in an active form. Despite being a prodrug, Vyvanse still has the same black box warning as other amphetamines concerning addiction and abuse.
- 62. Upon information and belief, Shire sales representatives and medical science liaisons ("MSLs") erroneously promote that Vyvanse is non-abuseable. Yet the study that supports this claim concludes that Vyvanse is subject to being abused. Consequently, any promotion that Vyvanse is "non-abuseable" constitutes an off-label promotion.
- 63. Moreover, such promotion and marketing represents an immediate and serious health risk to the public.
- 64. The health risks surrounding Adderall XR and Vyvanse are magnified because these drugs impact the central nervous system and Vyvanse can be prescribed for children.

- 65. Shire's success in the promotion of Vyvanse as "non-abuseable" is memorialized in a November 2007 copied to a number of Shire high-ranking management, including Relator-Plaintiff.
- 66. That email discusses a presentation given by Russell Barkley, Ph.D. on November 7, 2007 at Theda Care Behavioral Health in Appleton, Wisconsin. It was reported that 800-900 people attended Dr. Barkley's presentation.
- 67. Dr. Barkley is an internationally-recognized authority on ADHD. Internally at Shire he is known as an "ADHD guru."
- 68. According to this internal, widely-generated email, Dr. Barkley stated the following about Vyvanse:

Vyvanse is a PRO DRUG. The FDA granted this medication a new class for the treatment of ADHD. Vyvanse is unlike anything we have ever had. It's really cool. *You can't abuse Vyvanse because it only is metabolized in your stomach, which is absolutely fascinating.* What's really interesting is that the company stumbled upon the fact that it lasts 12-14 hours. (emphasis added)

- 69. Upon information and belief, Dr. Barkley learned this blatantly false marketing message from Shire MSL Jennifer Robinson. It was reported that Jennifer Robinson met with Dr. Barkley four times in the year preceding Dr. Barkley's statement.
- 70. In fact, upon information and belief, Shire uses MSLs to promote false and misleading information about its products to key opinion leaders.
- 71. The "non-abuseablity" message is referred to as a "branded message" by senior management at Shire.

E. Shire Improperly Markets Adderall XR for Various Treatments

- 72. Shire used medical letters that contained either false or misleading information to promote Adderall XR as effective in the treatment of Conduct Disorder and Oppositional Defiant Disorder.
- 73. Upon information and belief, Shire promotes Adderall XR for the treatment of Conduct Disorder and Oppositional Defiant Disorder. Both Conduct Disorder and Oppositional Defiant Disorder are distinct illnesses from ADHD. The promotion of Adderall XR for the treatment of Conduct Disorder and Oppositional Defiant Disorder constitutes off-label promotions.
- 74. On September 25, 2008, the FDA issued a Warning Letter (the "September 2008 Letter") to Shire for posting a video testimonial that overstated the efficacy of Adderall XR, omitted important safety information about the risks associated with Adderall XR and broadens the FDA indication for Adderall XR.
- 75. According to the September 2008 Letter, Adderall XR has numerous contraindications, including but not limited to patients with advance arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism and patients with a history of drug abuse.
- 76. Also according to the September 2008 Letter, Adderall XR is associated with "a number of serious risks, some of which may be fatal." These risks "include serious cardiovascular events, hypertension, psychiatric events, aggression, long-term suppression of growth, seizures and visual disturbances."
- 77. The September 2008 Letter states that the webpage implies that Adderall XR reduces the likelihood or severity of the difficulties and consequences of untreated ADHD such

as increased injury rates, increased sexually transmitted diseases, co-morbid conduct disorder and poor academic performance. None of these claims were supported by substantial evidence or substantial clinical experience.

- 78. The September 2008 Letter states that the video was not submitted to the FDA under cover of form FDA 2253 as required by CFR 314.81(b)(3)(i). Relator-Plaintiff has specific knowledge that Shire also failed to submit other advertising material under cover of form FDA 2253 as required by CFR 314.81(b)(3)(i).
- 79. Relator-Plaintiff has specific knowledge that Shire promoted Adderall XR improperly not only to viewers of the webpage but also in visual aids and other media to doctors from 2001 onwards. Specifically, Shire promoted that untreated ADHD is associated with a greater incidence of unemployment, tobacco addiction, criminal arrest, alcohol abuse and traffic violations. Concurrent promotion of these overstated data with Adderall XR implies that usage of Adderall XR will prevent a person from becoming addicted to tobacco, getting arrested, abusing alcohol, etc. This promotion, which preceded the September 29, 2008 Warning Letter, constituted a false and/or misleading promotion of Adderall XR.
- 80. All of Shire's "off-label" promotional activities constituted false and fraudulent statements as a matter of law under the Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 331(a) and (b), 352(a) and (f) and regulations promulgated by the FDA to implement the FDCA.
- 81. Shire knew and intended that its "off-label" promotional campaign would improperly increase the submission of prescriptions for Adderall XR and Vyvanse, including those prescriptions reimbursed by the Medicare and Medicaid programs.

- 82. Absent Shire's illegal and improper marketing schemes, and its false statements concerning Adderall XR, Vyvanse and Daytrana, physicians would not have believed that it was medically prudent or necessary to write so many prescriptions for those drugs.
- 83. Shire's illegal and improper marketing schemes and programs have been extremely successful leading to the submission of claims to the Medicare and Medicaid programs for medically unnecessary and imprudent prescriptions which others would not have been paid by Medicare and Medicaid.
- 84. Relator-Plaintiff believes and therefore avers that Shire has used inappropriate inducements (i.e. payments to physicians) to improperly promote Adderall XR and Vyvanse.

F. Shire Sales Representatives Completed "Prior Authorization" Forms For Providers

- 85. Medicaid is a joint federal-state program designed to afford medical benefits to low-income individuals. *See* 42 U.S.C.1396 *et seq*. Medicaid is cooperatively funded by the federal and individual state governments, with the federal government paying the majority of most states' medical expenses.
- 86. Under the Medicaid Act, states must pay for certain services provided to Medicaid recipients. Services that are eligible for mandatory payment include inpatient and outpatient hospital services, rural health clinic services, laboratories and x-ray services, nursing facility services, pregnancy-related services, physician services and home health services. *See* 42 U.S.C § 1396d(a)(1)-(5), (17) and (21); 42 C.F.R. §440.210 However, states can also chose to cover other, "optional" services. These services include pharmacy (prescription) services, private duty nursing services, dental services, durable medical equipment; hospice, case management, and any other medical care recognized under state law and approved by the Secretary of HHS. 42 U.S.C. § 1396d(a)(6)-(16), (18)- (19); 42 U.S.C. § 1396n(g).

- 87. Outpatient prescription drugs will be a major source of Medicaid spending particularly for the elderly and people with disabilities.
- 88. To keep budgets manageable, states are attempting to curb these costs. The Medicaid Act allows states to use a number of utilization controls on the use of services to control costs and to ensure that only medically necessary services are reimbursed. *See* 42 U.S.C. § 1396a(a)(30). *See also* 42 C.F.R. §§ 440.230(d), 456.1.
- 89. A state Medicaid agency may apply utilization controls to prescription drugs provided through the Medicaid program. These controls may consist of a requirement for "prior authorization," exclusion of specific drugs, limits on the number of brand name drugs that can be prescribed for a patient or a requirement that drugs be on a "preferred" list in order to be covered. "Prior authorization" means that the state requires prior approval of an otherwise covered outpatient drug. See 42 U.S.C. § 1396r-8(d)(5). Prior authorization should be administered by "qualified" professionals. *Id*.
- 90. Although the information that must be submitted as part of the prior approval process varies, a proper request for prior approval must include the recipient's name, address, Medicaid identification (MID) number, and date of birth, as well the provider's contact information (including signature, if required) and provider number, the date of the request, and clinical information pertinent to the product, service, or procedure being requested.
- 91. In or around October 2008, Relator became aware that several Shire sales representatives had filled out and submitted prior authorization requests for several of Shire pharmaceutical products by impersonating "qualified" professionals and/or office staff.
- 92. These events were investigated by the Corporate Compliance Department at Shire, and initially thought to be restricted to only two sales representatives.

- 93. However during the investigation, this behavior was found to be much more widespread.
- 94. Upon information and belief, numerous Shire sales representatives were completing and submitting "prior authorization" forms for providers for Adderall XR and Vyvanse.
- 95. Moreover, these actions by Shire sales representatives may also violate the *Privacy Rule* of HIPAA because, in order to process the prior authorization, the sales representatives needed to obtain clinical information and "common identifiers" of the patient/recipient.
- 96. The *Privacy Rule*, enacted by HHS in August 2002, protects all "individually identifiable health information" held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. The *Privacy Rule* calls this information "protected health information (PHI)."
- 97. Shire sales representatives clearly would not have had, and should not have had, access to this "protected health information."

G. Defendants Manufactured, Marketed and Sold Defective Daytrana Patches

- 98. Daytrana is a transdermal patch which contains the stimulant methylphenidate.
- 99. Daytrana is licensed globally to Shire by Noven Pharmaceuticals.
- 100. Daytrana was developed, and is manufactured, by Noven Pharmaceuticals but is sold and marketed by Shire.
 - 101. Shire designed, administered and managed the phase II and III trials of Daytrana.
- 102. During the phase III clinical trials, study sites reported that users were having numerous difficulties with the Daytrana patch.
- 103. In late 2004, representatives from Shire contacted the study site coordinators by letter to inform them that the difficulties with using the patch would be ameliorated if the patch

was refrigerated. The current custodian of this document at Shire is Arnaud Partiot. This communication was never shared with the FDA.

- 104. Both the difficulties with using the patch in the clinical trials and the defendant's instructions to refrigerate the patch were not shared with the FDA in Daytrana's New Drug Application ("NDA"). Thus the subsequent FDA approval of Daytrana was predicated on false claims of safety and efficacy and Daytrana. Consequently, payments for Daytrana were predicated on false claims.
- 105. Daytrana was approved by the FDA on April 6, 2006 to treat ADHD in children six to twelve years old.
 - 106. In 2006, Daytrana had global sales of approximately \$25.1 million.
 - 107. In 2007, Daytrana had global sales of approximately \$64.2 million.
 - 108. In 2008, Daytrana had global sales of approximately \$79 million.
- 109. On August 4, 2008, Noven Pharmaceuticals announced that net Daytrana sales had exceeded \$75 million for the twelve months preceding June 30, 2008 thus triggering a \$25 million sales milestone.
- 110. Since the launch of Daytrana in May 2006 there have been multiple voluntary market withdrawals ("VMW") of Daytrana.
- 111. The VMWs were instituted as a result of numerous patient complaints about the difficulty of removing the Daytrana patch's release liner which rendered the patches useless in many cases.
- 112. From launch until July 2007, Shire received more than 19,344 complaints about Daytrana patches. This constituted approximately 4-5% of all Daytrana users during this time

period. It is believed that substantially more patients had difficulty with the patch but failed to report their difficulties to the company.

- 113. On January 4, 2008, Defendant Noven received an FDA Warning Letter outlining violations of the Federal Food, Drug and Cosmetic Act (the "FDCA"). Specifically, the FDA found that the manufacture, processing, packing or holding of Daytrana "do not conform to or are not operated or administered in conformity with Current Good Manufacturing Practices (cGMP) regulations for drugs specified in Title 21, Code of Federal Regulations (CFR), part 211."
- 114. The Warning Letter identifies numerous problems with the Daytrana patch including, but not limited to, "adhesive transfer" and "tight release".
- 115. In sum, Noven Pharmaceuticals failed to manufacture Daytrana to the specifications required under applicable under federal law. For its part, Shire knowingly sold, distributed and marketed defective Daytrana patches. Consequently, any sales of the Daytrana patches that were the subject of the January 4, 2008 Warning Letter that were paid for by Medicare or Medicaid constituted false claims.
- 116. Upon information and belief, approximately 20% of the prescriptions for Daytrana are paid for by the state and/or federal governments.
- 117. Relator-Plaintiff believes, and therefore avers, that Shire withheld material information from FDA regarding the safety and efficacy of Daytrana.

COUNT 1 Violations of False Claims Act 31 U.S.C. § 3729

118. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.

- 119. This Count is brought by Relator-Plaintiff in the name of the United States against the Defendant under the *qui tam* provisions of 31 U.S.C. § 3730 for Defendant's violation of 31 U.S.C. § 3729(a)(1) and (a)(2). In violation of 31 U.S.C. § 3729(a)(1) and (a)(2), Defendant made and caused to be made, the false claims that have been set forth in the Fifth Amended Complaint herein.
- 120. Plaintiff United States, unaware of the falsity of the claims and/or statements which Defendant caused doctors, pharmacists, and other health care providers to make to the United States, and in reliance on the accuracy thereof, paid those doctors, pharmacies and other health care providers for claims that would otherwise not have been allowed.
 - 121. The amounts of the false or fraudulent claims to the United States were material.
- 122. Plaintiff United States, being unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy thereof, paid and may continue to pay Defendant for health care services that otherwise should not have been paid under the Medicaid, CHAMPUS/TRICARE, CHAMPVA, and the Federal Health Benefit Program, and other federal health care programs.
- 123. The United States and the state Medicaid programs have been damaged by the payment of false or fraudulent claims.

a. That by reason of the aforementioned violations of the False Claims Act this

Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three (3)

times the amount of damages that the United States has sustained because of Defendants'

actions, plus a civil penalty not less than \$5,000 nor more than \$10,000 for each violation of 31 U.S.C. § 3729;

- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act and/or any other applicable provision of the law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Relator-Plaintiff has such other and further relief that this Court deems just and proper.

COUNT 2 Conspiracy to Submit False Claims 31 U.S.C. § 3729(a)(3)

- 124. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein
- 125. By effectuating the schemes detailed herein, the Shire defendants conspired to defraud the government by causing the submission of false claims for Adderall XR and Vyvanse.
- 126. By effectuating the schemes detailed herein, Shire and Noven conspired to defraud the government by causing the submission of false claims for Daytrana.
- 127. As a result of the claims for reimbursement that Defendants caused to be submitted to Medicaid, the government improperly made payments for Adderall XR, Vyvanse and Daytrana.
 - 128. The amounts of the false or fraudulent claims to the government were material.
- 129. Plaintiff United States, being unaware of the falsity of the statements caused to be made by Defendants, and in reliance on the accuracy thereof, paid and may continue to pay for improper claims related to Adderall XR, Vyvanse and Daytrana.

130. From at least 2002 through the date of this Fifth Amended Complaint, by reason of the conduct described above, the government has been damaged.

WHEREFORE, Plaintiffs demand judgment against defendants Shire and Noven as follows:

- a. That by reason of the aforementioned violations of the False Claims Act this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three (3) times the amount of damages that the United States has sustained because of Defendants' actions, plus a civil penalty not less than \$5,000 nor more than \$10,000 for each violation of 31 U.S.C. § 3729;
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act and/or any other applicable provision of the law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Relator-Plaintiff has such other and further relief that this Court deems just and proper.

COUNT 3 Violation of Arkansas Medicaid Fraud False Claims Act, Ark. Code Ann. § 20-77-901 et seg.

- 131. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 132. This is a claim for treble damages and civil penalties under the Arkansas Medicaid Fraud False Claims Act, Ark. Code Ann. § 20-77-901.
- 133. By virtue of the above-described acts, among others, Defendants knowingly presented or caused to be presented to the Arkansas Medicaid Program false or fraudulent claims

for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.

- 134. The Arkansas Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.
- 135. By reason of these payments, the Arkansas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

WHEREFORE, Plaintiffs demand judgment against defendants Shire and Noven as follows:

- a. That by reason of the aforementioned violations of the Arkansas false claims provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that Arkansas has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of Section 20-77-902;
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to Section 20-77-911 and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper

COUNT 4 Violations of California False Claims Act Cal. Government Code §§ 12650-12655

136. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.

- 137. This is a claim against Defendants for treble damages and penalties on behalf of the State of California under the California False Claims Act, California Government Code §§ 12650-12655.
- 138. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.
- 139. By virtue of the above-described unlawful acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims under the Medicaid program.
- 140. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.
- 141. By reason of Defendants' conspiracy and unlawful acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.
- 142. The State of California is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

a. That by reason of the aforementioned violations of the California False Claims

Act that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal

to not less than two times and not more than three times the amount of damages that California has sustained because of Defendants' actions, plus a civil penalty of not more than \$10,000 for each violation of CAL. GOV. CODE §12651(a)(3);

- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to CAL. GOV. CODE §12652(g)(2) and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 5 Violations of Colorado's Medicaid False Claims Act, C.R.S. §§ 25.5-4-303.5 et seq.

- 143. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 144. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act, C.R.S. §§ 25.5-4-303.5 et seq.
- 145. By virtue of the above-described acts, among others, Defendants knowingly presented or caused to be presented to the Colorado Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used a false record or statement.
- 146. The Colorado Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.
- 147. By reason of these payments, the Colorado Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

- a. That by reason of the aforementioned violations of the Colorado false claims provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times the amount of damages that Colorado has sustained because of Defendants' actions, plus a civil penalty of not less than \$10,000 for each violation of Section 25.5-4-305;
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to Sections 25.5-4-306 and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 6

Violation of Connecticut's False Claims Act Connecticut Medical Assistance Program False Claims Act, § 17b-301a et. seq.

- 148. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 149. This is a claim for treble damages and penalties against the Defendants on behalf of the Connecticut Medical Assistance Program False Claims Act, § 17b-301a et. seq.
- 150. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.
- 151. By virtue of the above-described acts, Defendants knowingly made, used, or cause the State of Connecticut to approve and pay such false and fraudulent claims.

152. By reason of these payments, the Connecticut Medicaid Program has been damaged, and continues to be damaged in a substantial amount

WHEREFORE, Plaintiffs demand judgment against defendants Shire and Noven as follows:

- a. That by reason of the aforementioned violations of the Connecticut false claims provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that Connecticut has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of the CFCA;
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to the CFCA and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 7 Delaware False Claims and Reporting Act 6 Del C. §1201(a)(1) and (2)

- 153. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 154. This is a claim for treble damages and penalties against Shire on behalf of the State of Delaware under the Delaware False Claims and Reporting Act, 6 Del C. §1201(a)(1) and (2).
- 155. By virtue of the above-described acts, among others, Defendant Shire did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.

- 156. By virtue of the above-described acts, Defendant knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.
- 157. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.
- 158. By reason of Defendant's conspiracy and unlawful acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.
- 159. The State of Delaware is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

- a. That by reason of the aforementioned violations of the Delaware false claims provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that Delaware has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,500 and not more than \$11,000 for each violation of DEL. CODE ANN. TIT. 6 §1201(a)(3);
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to DEL. CODE ANN. §1205(a) and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 8 Violations of Florida's False Claims Act Fl. Stat. §68.081-68.090

- 160. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 161. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Florida under the Florida False Claims Act, Fl. Stat. §68.081-68.090.
- 162. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.
- 163. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.
- 164. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.
- 165. By reason of the Defendants' unlawful acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.
- 166. The State of Florida is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

- a. That by reason of the aforementioned violations of the Florida false claims provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that Florida has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of FLA. STAT. ANN. §68.082(2)(a)(3);
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant FLA. STAT. ANN. §68.085(1)-(2) and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 9 Violations of Georgia's False Medicaid Claims Act Ga. Code 49-4-168 et seq.

- 167. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 168. This is a claim for treble damages and penalties against the Defendant on behalf of the State of Georgia under the Georgia State False Medicaid Claims Act, Ga. Code 49-4-168 et seq.
- 169. By virtue of the above-described acts, among others, Defendans did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.

- 170. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.
- 171. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.
- 172. By reason of the Defendants' unlawful acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.
- 173. The State of Georgia is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

- a. That by reason of the aforementioned violations of the Georgia False Medicaid Claims Act that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the Georgia has sustained because of Defendants' actions, plus a civil penalty of not more than \$10,000 for each violation of the GA. CODE ANN. § 49-4-168.1;
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant the GA. CODE ANN. § 49-4-168.2 (I) and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 10 Violations of Hawaii's False Claims Act HAW. REV. STAT. §§661-21 to 661-29

- 174. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 175. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Hawaii under the HAW. REV. STAT. §661-21(a)(3).
- 176. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.
- 177. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.
- 178. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.
- 179. By reason of the Defendants' unlawful acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.
- 180. The State of Hawaii's Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against defendants Shire and Noven as follows:

- a. That by reason of the aforementioned violations of the Hawaii's false claim provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that Hawaii has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of HAW. REV. STAT. §661-21(a)(3);
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant HAW. REV. STAT. §661-27(a) and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 11 Violations of Illinois' Whistleblower Reward and Protection Act 740 ILCS 175/1 et seg.

- 181. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 182. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Illinois under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 17511 *et seq*.
- 183. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.

- 184. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.
- 185. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.
- 186. By reason of the Defendants' unlawful acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.
- 187. The State of Illinois is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

- a. That by reason of the aforementioned violations of the Illinois Whistleblower Reward and Protection Act that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that Illinois has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of ILL. COMP. STAT. 175/3(a)(3);
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant ILL. COMP. STAT. 175/4(d)(1) and/or any other applicable provision of law;

- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 12

Violations of Indiana's False Claims and Whistleblowers Protection Act, IND. CODE ANN. § 5-11-5.5-1 – 5-11-5.5-18

- 188. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 189. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Indiana under the Indiana State False Claims and Whistleblowers Protection Act, IND. CODE ANN. § 5-11-5.5-1 5-11-5.5-18.
- 190. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.
- 191. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.
- 192. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.
- 193. By reason of the Defendant's unlawful acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

- a. That by reason of the aforementioned violations of the Indiana State False Claims and Whistleblowers Protection Act that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the Indiana has sustained because of Defendants' actions, plus a civil penalty of less than \$5,000 for each violation of the IND. CODE ANN. § 5-11-5.5-2;
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant the IND. CODE ANN. § 5-11-5.5-6 and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 13

Violations of Louisiana's Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1 et seq.

- 194. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 195. This is a claim for treble damages and penalties against all Defendant on behalf of the State of Louisiana under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1 *et seq*.
- 196. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.

- 197. By virtue of the above-described acts, Defendants knowingly made, used, or Louisiana State Government to approve and pay such false and fraudulent claims.
- 198. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.
- 199. By reason of the Defendants' unlawful acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

- a. That by reason of the aforementioned violations of the Louisiana False Claims

 Act provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an

 amount three times the amount of damages that Louisiana has sustained because of Defendants'

 actions for violation of the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat.

 Ann. § 46:439.1 et seq.;
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1 *et seq.* and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 14 Violation of Maryland False Claims Act, Md. Code Ann. §2-601 et seq.

- 200. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 201. This is a claim for treble damages and civil penalties under the Maryland False Health Claims Act of 2010, Md. Code Ann. § 2-601 et seq.
- 202. By virtue of the above-described acts, among others, Defendants knowingly presented or caused to be presented to the Maryland Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement.
- 203. The Maryland Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.
- 204. By reason of these payments, the Maryland Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

- a. That by reason of the aforementioned violations of the Maryland false claims provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not more than three times the amount of damages that Maryland has sustained because of Defendants' actions, plus a civil penalty of not more than \$10,000 for each violation of Section 2.602 *et seq.*;
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to Sections 2.605 and/or any other applicable provision of law;

- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 15 Massachusetts False Claims Act Massachusetts Gen. Laws c.12 §5(A)

- 205. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 206. This is a claim for treble damages and penalties against the Defendants on behalf of the Commonwealth of Massachusetts under the Massachusetts False Claims Act, Massachusetts Gen. Laws c.12 §5(A).
- 207. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.
- 208. By virtue of the above-described acts, Defendants knowingly made, used, or caused the Commonwealth of Massachusetts to approve and pay such false and fraudulent claims.
- 209. The Commonwealth of Massachusetts, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.
- 210. By reason of the Defendants' unlawful acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

- a. That by reason of the aforementioned violations of the Massachusetts False Claims Act provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount three times the amount of damages that Louisiana has sustained because of Defendants' actions for violation of the Massachusetts False Claims Act, Massachusetts Gen. Laws c.12 §5(A);
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant Massachusetts False Claims Act, Massachusetts Gen. Laws c.12 §5(A) and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 16 Violation of the Michigan Medicaid False Claims Act MICH. COMP LAWS § 400.601-400.613

- 211. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 212. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.
- 213. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

- 214. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.
- 215. By reason of the Defendants' unlawful acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amount to be determined at trial.
- 216. The Michigan State Medicaid Program has been damaged by the payment of false and fraudulent claims.

- a. That by reason of the aforementioned violations of the Michigan State Medicaid False Claims Act that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to three times the amount of damages that the Michigan has sustained because of Defendants' actions, plus a civil penalty of equal to the full amount Shire unjustly received as a result of its unlawful conduct for violating MICH. COMP LAWS § 400.603, 606 and 607;
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant the MICH. COMP LAWS § 400.610 and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 17

Violation of Minnesota's False Claims Act Minnesota False Claims Act, § 15C.01 et seq.

- 217. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 218. This is a claim for treble damages and penalties against the Defendants on behalf of the Minnesota False Claims Act, § 15C.01 et seq.
- 219. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.
- 220. By virtue of the above-described acts, Defendants knowingly made, used, or cause the State of Minnesota to approve and pay such false and fraudulent claims.
- 221. The Minnesota State Medicaid Program has been damaged by the payment of false and fraudulent claims.

- a. That by reason of the aforementioned violations of the Minnesota false claims provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that Minnesota has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of Section 15C.01 *et seq.*;
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to Sections 15C.12 and 15C.13 and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 18 Violation of the Montana False Claims Act MONT. CODE ANN. § 17-8-401 – 17-8-412

- 222. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 223. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.
- 224. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Montana State Government to approve and pay such false and fraudulent claims.
- 225. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.
- 226. By reason of the Defendants' unlawful acts, the State of Montana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.
- 227. The Montana State Medicaid Program has been damaged by the payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against defendants Shire and Noven as follows:

a. That by reason of the aforementioned violations of the Montana False Claims Act that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to

not less than two times and not more than three times the amount of damages that the Montana has sustained because of Defendants' actions, plus a civil penalty of not more than \$10,000 for each violation of the MONT. CODE ANN. § 17-8-403;

- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant the MONT. CODE ANN. § 17-8-410 and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 19 Nevada False Claims Act NEV. REV. STAT. ANN. §357.01-.250

- 228. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 229. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Nevada under the Nevada False Claims Act. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FD
- 230. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.
- 231. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

- 232. By reason of the Defendants' unlawful acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.
- 233. The State of Nevada is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

- a. That by reason of the aforementioned violations of the Nevada false claims provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that Nevada has sustained because of Defendants' actions, plus a civil penalty of not more than \$10,000 for each violation of the NEV. REV. STAT. ANN. §357.014(1)(c);
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant Nev. Rev. Stat. Ann. §357,210(1) and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 20 New Hampshire False Claims Act N.H. REV. STAT. ANN. § 167:58-167:61-b

234. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.

- 235. This is a claim for treble damages and penalties against Defendants on behalf of the State of New Hampshire under the New Hampshire False Claims Act, N.H. REV. STAT. ANN. §167:61-b.
- 236. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.
- 237. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Hampshire State Government to approve and pay such false and fraudulent claims.
- 238. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.
- 239. By reason of the Defendants' unlawful acts, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amount to be determined at trial.
- 240. The State of New Hampshire is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

a. That by reason of the aforementioned violations of the New Hampshire false claims provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of

damages that New Hampshire has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of the N.H. REV. STAT. ANN. §167:61-b;

- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant N.H. REV. STAT. ANN. §167:61-b and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 21 New Jersey False Claims Act N.J. STAT. §2A:32C-1-17

- 241. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 242. This is a claim for treble damages and penalties against the Defendants on behalf of the State of New Jersey under the New Jersey False Claims Act N.J. STAT. §2A:32C-1-17.
- 243. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.
- 244. By virtue of the above-described acts, Defendants knowingly made, used, or cause the State of New Jersey to approve and pay such false and fraudulent claims.
- 245. The State of New Jersey, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and

continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

246. By reason of the Defendants' unlawful acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

WHEREFORE, Plaintiffs demand judgment against defendant Shire and Noven as follows:

- a. That by reason of the aforementioned violations of the New Jersey False Claims provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the state of New Jersey has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of N.J. STAT. §2A:32C-1-17;
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant N.J. STAT. §2A:32C-1-17 and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 22 New Mexico Medicaid False Claims Act, N.M. STAT. ANN. § 27-14-1- - 27-14-15

247. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.

- 248. This is a claim for treble damages and penalties against all Defendants on behalf of the State of New Mexico under the New Mexico Medicaid False Claims Act, N.M. STAT. ANN. § 27-14-1- 27-14-15.
- 249. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.
- 250. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.
- 251. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.
- 252. By reason of the Defendants' unlawful acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

- a. That by reason of the aforementioned violations of the New Mexico False Claims Act provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount three times the amount of damages that New Mexico has sustained because of Defendants' actions for violation of the N.M. STAT. ANN. § 27-14-4;
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant N.M. STAT. ANN. § 27-14-9 and/or any other applicable provision of law;

- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 23

New York False Claims Act N.Y. St. Finance Law §187 et seq.

- 253. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 254. This is a claim for treble damages and penalties against all Defendants on behalf of the State of New York under the New York False Claims Act, N.Y. St. Finance Law §187 et seq.
- 255. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.
- 256. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.
- 257. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.
- 258. By reason of the Defendants' unlawful acts, the State of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

259. The State of New York is entitled to the maximum penalty of \$12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

WHEREFORE, Plaintiffs demand judgment against defendants Shire and Noven as follows:

- a. That by reason of the aforementioned violations of the New York False Claims

 Act provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an

 amount equal to not less than two times and not more than three times the amount of damages

 that New York has sustained because of Defendants' actions, plus a civil penalty of not less than

 \$6,000 and not more than \$12,000 for each violation of N.Y. STATE FIN. LAW § 189;
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant N.Y. STATE FIN. LAW § 119(6) and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 24 Violations of North Carolina False Claims Act, N.C.G.S §§1-605 et seq.

- 260. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 261. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N.C.G.S §§1-605 et seq.
- 262. By virtue of the above-described acts, among others, Defendants knowingly presented or caused to be presented to the North Carolina Medicaid Program false or fraudulent

claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used a false record or statement.

- 263. The North Carolina Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.
- 264. By reason of these payments, the North Carolina Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

WHEREFORE, Plaintiffs demand judgment against defendants Shire and Noven as follows:

- a. That by reason of the aforementioned violations of the North Carolina false claims provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that North Carolina has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of Section 1-607;
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to Section 1-610 and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 25 Violation of Oklahoma's False Claims Act 63 Okl. St. §5053-5053.7

265. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.

- 266. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.
- 267. By virtue of the above-described acts, Defendant knowingly made, used, or cause the State of Oklahoma to approve and pay such false and fraudulent claims.
- 268. By reason of the Defendants' unlawful acts, the State of Oklahoma has been damaged, and continues to be damaged, in substantial amount to be determined at trial

- a. That by reason of the aforementioned violations of Oklahoma's False Claims provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the state of Oklahoma has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of 63 Okl. St. §5053.1.4;
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant 63 Okl. St. §5053.1.4 and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

Violation of Rhode Island's State False Claims Act R.I. Gen. Laws § 9-1.1-1 – 9-1.1-8

269. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.

- 270. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Rhode Island's False Claims Act R.I. Gen. Laws § 9-1.1-3.
- 271. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.
- 272. By virtue of the above-described acts, Defendant knowingly made, used, or cause the State of Rhode Island to approve and pay such false and fraudulent claims.
- 273. By reason of the Defendants' unlawful acts, the State of Rhode Island has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

- a. That by reason of the aforementioned violations of Rhode Island's False Claims provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the state of Rhode Island has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of R.I. Gen. Laws § 9-1/1-3;
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant R.I. Gen. Laws § 9-1.1-4(d) and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 27 Tennessee Medicaid False Claims Act Tenn. Code. Ann. §71-5-181 to -185

- 274. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 275. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Tennessee under the Tennessee Medicaid False Claims Act.
- 276. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.
- 277. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.
- 278. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.
- 279. By reason of the Defendants' unlawful acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amount to be determined at trial.
- 280. The State of Tennessee is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

- a. That by reason of the aforementioned violations of the Tennessee false claims provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that Tennessee has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of the TENN. CODE ANN. §71-5-182(a)(1)(C);
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant Tenn. Code. Ann. §71-5-183(c)(1) and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 28 Texas Medicaid Fraud Prevention Act TEX. HUM. RES. CODE ANN 36.001-.132

- 281. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 282. This is a claim for treble damages and penalties against the Defendants on behalf of the State of Texas under the Texas Medicaid Fraud Prevention Act, TEX. HUM. RES. CODE ANN.36.001–.132.
- 283. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.

- 284. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.
- 285. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendant's illegal inducements and/or business practices.
- 286. By reason of the Defendants' unlawful acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.
- 287. The State of Texas is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

a. That by reason of the aforementioned violations of the Texas Medicaid Fraud Prevention Statute that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to two times the amount of damages that the state of Texas has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,000 and not more than \$15,000 for each violation of TEX. HUM. RES. CODE ANN. § 36.002(8) that results in injury to an elderly person, a disabled person, or a person younger than 18 years of age, or not less than \$1,000 and not more than \$10,000 for each violation of the TEX. HUM. RES. CODE ANN. § 36.002(8) that does not result in an injury to a person;

- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant TEX. HUM. RES. CODE ANN. § 36.110 and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 29 Violations of Utah's False Claims Act, Utah Code Ann. § 26-20-1, et seq.

- 288. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 289. This is a claim for treble damages and civil penalties under the Utah False Claims Act, Utah Code Ann. § 26-20-1 et seq.
- 290. Defendants violated the Utah False Claims Act as codified in the Utah Health Code at Title 26, Chapter 20 of the Utah Code Annotated.
- 291. By virtue of the misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Utah Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, or causing to be made or used a false record or statement.
- 292. The Utah Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendant, paid for claims that otherwise would not have been allowed.
- 293. By reason of these payments, the Utah Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

- a. That by reason of the aforementioned violations of the Utah False Claims Act that this Court enter judgment in Plaintiffs' favor and against Defendants for full and complete restitution to Utah for all damages that Utah sustained, a civil penalty equal to three times the restitution amount, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim filed;
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to the Utah False Claims Act and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper

COUNT 30 VIRGINIA FRAUD AGAINST TAXPAYERS ACT VA. CODE ANN. 8.01-216.1-216.19

- 294. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 295. This is a claim for treble damages and penalties against the Defendants on behalf of the Commonwealth of Virginia under the Virginia Fraud Against Taxpayers Act, Vested. Ch. 842, Article 19.1, § 8.01-216.1 *et seq*.
- 296. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.

- 297. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia State Government to approve and pay such false and fraudulent claims.
- 298. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.
- 299. By reason of the Defendants' unlawful acts, the Commonwealth of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.
- 300. The Commonwealth of Virginia is entitled to the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendant.

- a. That by reason of the aforementioned violations of the Virginia Fraud Against Taxpayers Act that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the Commonwealth of Virginia has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of the VA. CODE ANN. § 8.01-216.3(A)(3);
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant VA. CODE ANN. § 8.01-216.7 and/or any other applicable provision of law;

- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 31 Violation of Wisconsin's False Claims Act Wis. Stat. § 20.931

- 301. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 302. This is a claim for treble damages and penalties against the Defendant on behalf of the State of Wisconsin's False Claims Act Wis. Stat. § 20.931.
- 303. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.
- 304. By virtue of the above-described acts, Defendant knowingly made, used, or cause the State of Wisconsin to approve and pay such false and fraudulent claims.
- 305. By reason of the Defendants' unlawful acts, the State of Wisconsin has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

WHEREFORE, Plaintiffs demand judgment against defendants Shire and Noven as follows:

a. That by reason of the aforementioned violations of Wisconsin's False Claims provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the state of Wisconsin has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of Wis. Stat. § 20.931;

- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant Wis. Stat. § 20.931 and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 32 City of Chicago False Claims Act Municipal Code of Chicago §1-22-010-§1-22-060

- 306. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 307. This is a claim for treble damages and penalties against all Defendants on behalf of the City of Chicago under the Chicago False Claims Act, Municipal Code of Chicago §1-22-010-§1-22-060.
- 308. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.
- 309. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Chicago City Government to approve and pay such false and fraudulent claims.
- 310. The Chicago City Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

311. By reason of the Defendants' unlawful acts, the City of Chicago has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

WHEREFORE, Plaintiffs demand judgment against defendants Shire and Noven as follows:

- a. That by reason of the aforementioned violations of the Chicago False Claims Act provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the City of Chicago has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,000 and not more than \$15,000 for each violation of the Chicago False Claims Act, Municipal Code of Chicago §1-22-010-§1-22-060;
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to the Municipal Code of Chicago §1-22-010 and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 33

District of Columbia Procurement Reform Amendment Act Violation of D.C. CODE ANN. §§ 2-308.13-.15

- 312. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 313. This is a claim for treble damages and penalties against Defendants on behalf of the District of Columbia under the District of Columbia Procurement Reform Amendment Act.

- 314. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.
- 315. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.
- 316. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.
- 317. By reason of the Defendants' unlawful acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.
- 318. The District of Columbia is entitled to the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

a. That by reason of the aforementioned violations of the District of Columbia false claims provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the District of Columbia has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of DC. CODE ANN. §2-308.14(a)(3);

- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant DC. CODE ANN. §2-308.15(f)(1) and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

COUNT 34 New York City False Claims Act New York City Administrative Code §7-801-§7-810

- 319. Relator-Plaintiff incorporates by reference all paragraphs in this Fifth Amended Complaint as if fully set forth herein.
- 320. This is a claim for treble damages and penalties against the Defendants on behalf of the City of New York under the New York City False Claims Act, New York City Administrative Code §7-801-§7-810.
- 321. By virtue of the above-described acts, among others, Defendants did knowingly and willfully promote Adderall XR and Vyvanse in ways that are not in accordance with their FDA-approved labeling.
- 322. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York City Government to approve and pay such false and fraudulent claims.
- 323. The New York City Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

324. By reason of the Defendants' unlawful acts, the City of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

WHEREFORE, Plaintiffs demand judgment against defendants Shire and Noven as follows:

- a. That by reason of the aforementioned violations of the New York City False Claims Act provisions that this Court enter judgment in Plaintiffs' favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the City of New York has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,000 and not more than \$15,000 for each violation of the New York City False Claims Act, New York City Administrative Code §7-801-§7-810;
- b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant New York City Administrative Code § 704(i) and/or any other applicable provision of law;
- c. That Plaintiffs and Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and
- d. That Plaintiffs have such other and further relief that this Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff-Relator Gerardo Torres, M.D., on behalf of himself, the United States and the States and Cities, requests that judgment be entered against Defendants, ordering that:

(i) Defendants cease and desist from violating the False Claims Act, 31 U.S.C. 3 3729 et seq., and the State False Claims Acts;

- (ii) Defendants pay not less than \$5,500 and not more than \$11,000 for each violation of 31 U.S.C. § 3729, plus three times the amount of damages the United States has sustained because of Defendants' actions, plus the appropriate amount to the States under similar provisions of the State False Claims Acts;
- (iii) Relator-Plaintiff be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) and the equivalent provisions of the state statutes set forth above;
- (iv) Relator-Plaintiff be awarded all costs of this action, including attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d) and similar provisions of the State False Claims Acts;
- (v) Defendants be enjoined from concealing, removing, encumbering or disposing of assets which may be required to pay the civil monetary penalties imposed by the Court;
- (vii) Defendants disgorge all sums by which it has been enriched unjustly by its wrongful conduct; and
- (viii) The United States, the States and Cities, and Relator-Plaintiff recover such other relief as the Court deems just and proper.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff hereby demands a trial by jury.

Respectfully submitted,

SHELLER, P.C.

/s/ Brian J. McCormick, Jr.
Stephen A. Sheller
Brian J. McCormick, Jr.
SHELLER, P.C.
1528 Walnut Street, Floor 3
Philadelphia, PA 19102
(215) 790-7300
sasheller@sheller.com
bjmccormick@sheller.com

Attorneys for Relator-Plaintiff Gerardo Torres, M.D.

DATE: February 14, 2011

FILED

FEB 16 2011

MICHAELE, KUNZ, Clerk By Dep. Clerk

CERTIFICATE OF SERVICE

I hereby certify that on this 15th day of February 2011, I caused a copy of the foregoing Motion for Leave to File Fifth Amended Complaint, and supporting papers, to be served by certified, first-class mail, postage prepaid, upon:

Zane D. Memeger, Esq.	Elizabeth Valentine, Esquire
Paul Kaufman, Esq.	Assistant Attorney General
United States Attorney's Office	State of Michigan, Dept. of Attorney General
615 Chestnut Street	P.O. Box 30218
Suite 1250	Lansing, MI 48909
Philadelphia, PA 19106	e,
	As Team Leader, NAMFCU
Medicaid Fraud Control Unit of Arkansas	Medicaid Fraud Control Unit of Colorado
Office of the Attorney General	Office of the Attorney General
323 Center Street	1525 Sherman Street
Suite 200	2nd Floor
	Denver, CO 80203
Little Rock, AR 72201	Deliver, CO 80203
MILLIE IC A III A CM -I -I	Malinia Ford Contact Library Constitution
Medicaid Fraud Control Unit of Maryland	Medicaid Fraud Control Unit of North Carolina
Office of the Attorney General	Office of the Attorney General
200 St. Paul Place	3824 Barrett Drive
18th Floor	Suite 200
Baltimore, MD 21202	Raleigh, NC 27609
Medicaid Fraud Control Unit of Utah	FUL
Office of the Attorney General	FILED
5272 College Drive	FEB 16 2011
Suite 200	1 6 2011
Salt Lake City, UT 84123	MICHKEL I. IGING
,	MICHKEL L. KUNZ, Clerk By Dep. Clerk
	J Sop. Clerk

BRIAN J/MCCORMICK, JR.